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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,296	08/27/2001	Sithian Pandian	MBM1270	7256

7590 04/06/2005

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San Diego, CA 92121

EXAMINER

WHISENANT, ETHAN C

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,296

Applicant(s)

PANDIAN ET AL.

Examiner

Ethan Whisenant, Ph.D.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 DEC 04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 5-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>28 DEC 04</u> | 6) <input type="checkbox"/> Other: _____ |

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FINAL REJECTION

1. The applicant's Response (filed 28 DEC 04) to the Office Action has been entered. Following the entry of the claim amendments, **Claim(s) 1-24** is/are pending with Claims 5-24 withdrawn from consideration. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.
2. Please note that this application has been transferred to a different examiner within Art Unit 1634. See the closing paragraph of this action for details.

ABSTRACT

3. The abstract as amended has been entered.

35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) The invention was described in –

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

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5. **Claim(s) 1-4** is/are rejected under 35 U.S.C. 102(e) as anticipated by Urdea [US 5,656,731 (1997)].

Claim 1 is drawn to an amplification probe adapted to permit enhanced detectable labelling of a selected target nucleic acid target which probe comprises at least two regions of nucleic acid sequences: a first region including a homopolymeric sequence and a second region including more than two discretely labellable sequence units of more than one type.

Urdea teach a probe which comprises at least two regions of nucleic acid sequences: a first region including a homopolymeric sequence and a second region including more than two discretely labellable sequence units of more than one type. See, at least, for example Figure 1-2. Note region A : a first region including a homopolymeric sequence. Note also region B and C a second region including more than two discretely labellable sequence units of more than one type. Admittedly, the probe described by Urdea is not used exactly as recited in the claims, however, the intend use of a product does not further limit said product. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. *In re Casey* , 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963). See also *Ex parte Masham*, 2 USPQ2d (Bd. Pat. App. & Inter. (1987)).

Claim 2 is drawn to an embodiment of Claim 1 wherein the number of discretely labelable units range s from 3 to 50 in number. Urdea teach this limitation. See, at least , for example, Column 12, lines 12-20.

Claim 3 is drawn to an embodiment of Claim 1 wherein each labellable sequence unit comprises a sequence of nucleotide bases hybridizable to a complementary sequence on a labelling probe said probe covalently attached to a detectable chemical label. Urdea teach this limitation. See, at least, for example, Column 15, lines 47-54 and Column 16, line 51- Column 17, line 3.

Claim 4 is drawn to an embodiment of Claim 3 wherein the length of each sequence unit ranges from 16 to 100 nucleotides. Urdea teach this limitation. See, at least, for example, Column 8, lines 18-20.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

6. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are not deemed to be persuasive. The applicant traverses the rejection of Claim 1 arguing that Claim 1 as amended is not anticipated by Urdea because Urdea does not teach an amplification probe comprising two regions wherein the first region includes a homopolymeric region complementary to a sequence on a selected primary probe. In response the examiner points to Figure 1-1 noting that the region designated as A comprises a homopolymeric region. Again, the examiner readily admits that the probe described by Urdea is not used exactly as recited in the claims, however, it must again be reiterated that the intended use of a product does not further limit said product. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). See also *Ex parte Masham*, 2 USPQ2d (Bd. Pat. App. & Inter. (1987)).

CONCLUSION

7. **Claim(s) 1-4** is/are rejected and/or objected to for the reason(s) set forth above.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

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The fax number for this Examiner is (571) 273-0754. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

A handwritten signature in black ink, appearing to read 'EWhisenant', with a long horizontal stroke extending to the right.

ETHAN WHISENANT
PRIMARY EXAMINER

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